

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION
This document relates to:
Track Three Cases

MDL 2804
CASE NO. 17-MD-2804
HON. DAN AARON POLSTER

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS'
MOTION TO EXCLUDE THE OPINIONS OFFERED BY DR. G. CALEB
ALEXANDER**

August 18, 2021

Defendants have moved to exclude the testimony of Dr. G. Caleb Alexander in Phase One of the trial. The primary basis offered by Defendants in support of their motion is their contention that Dr. Alexander's testimony is limited to the topic of abatement and is therefore irrelevant during the liability phase of this case. For the reasons given below, Defendants' arguments are without merit and their motion should be denied in whole. Plaintiffs incorporate the legal standard set forth in Plaintiffs' Opposition to Certain Defendants' *Daubert* Motion to Exclude the Opinions Offered by James Rafalski, filed contemporaneously, as if set forth fully herein.

Dr. G. Caleb Alexander is a Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health and a practicing general internist. Expert Witness Report of G. Caleb Alexander, MD, MS, Dkt. 3852, Alexander Rpt., ¶ 1. As a pharmacoepidemiologist, much of Dr. Alexander's work has focused on the nature, quality, and determinants of prescription drug utilization in the United States. *Id.* at ¶ 3. He has published more than 100 academic articles on opioids, including analyses of prescription opioid use in the U.S.; evaluations of the structure and impact of regulatory and payment policies on opioid prescribing, dispensing, and utilization; studies of opioid initiation among members of households with a prescription opioid user; the costs and healthcare utilization associated with high-risk opioid use, use of automated algorithms to identify non-medical opioid use; and the relationship between high-risk patients receiving prescription opioids and high-volume prescribers, among other topics. *Id.* at ¶¶ 5-6.

As Plaintiffs' expert in this case, Dr. Alexander (i) reviewed epidemiological data on opioids and opioid-related harms nationally and in Lake and Trumbull Counties and concluded that an opioid epidemic currently exists in those communities,¹ (ii) identified

¹ See, e.g., *id.* at ¶¶ 18, 20-28, 118-120, 150, 166-168, 175, 185, 194, 201-204, and 210-211, as well as other parts of Dr. Alexander's report that relate to the epidemiology of the opioid crisis and its effects on individuals, communities, and the health care delivery system.

the evidence-based measures and approaches that should be used in the Counties to reduce opioid-related morbidity and mortality,² (iii) estimated the size of specific populations within the Communities requiring abatement interventions over a 15-year period, from 2021 to 2035,³ and (iv) analyzed the scientific evidence for potential indicators of high-risk opioid distribution and the role that pharmacies and pharmacists play in addressing the opioid epidemic.⁴

Phase One of the upcoming trial in this matter concerns “whether a public nuisance exists; and [] if so, was any defendant a substantial factor in causing it?” Doc. 3579, pp. 3-4. In Phase One, Plaintiffs may call Dr. Alexander to testify as to the existence and impact of an opioid epidemic nationally and in Lake and Trumbull Counties (subpart *i* in the paragraph above). As an epidemiologist, Dr. Alexander’s opinions on these topics are highly relevant and would be helpful to the Court in understanding the scope of harms caused by the oversupply of prescription opioids into the jurisdictions. Consistent with methodologies used by epidemiologists, in reaching his conclusions, Dr. Alexander considered information from a variety of sources, including data and reports from federal agencies, local government entities, public health authorities, and non-profit organizations, among others – on opioid-involved deaths, opioid-related hospitalizations, individuals with opioid addiction, and the effects of the epidemic on children and families, pregnant women, people with opioid misuse, and other subpopulations – as well as the academic literature, and interviews with local stakeholders in the communities.

Plaintiffs may also call Dr. Alexander to testify about his analysis of the scientific literature on potential indicators of high-risk opioid distribution and the role that pharmacies and pharmacists play in addressing the opioid epidemic (subpart *iv* above).

² See *id.*, parts of §§ IV-VIII.

³ See *id.*, Appx. E.

⁴ See *id.*, Appx. F.

Such matters are relevant to actions Defendants could or should have taken to prevent diversion of opioid pharmaceuticals and resulting harms. For example, Dr. Alexander writes that indicators “based on opioid dose and duration are also important because there is an unequivocal dose-response association between opioid dose and duration and opioid-related morbidity and mortality.” Dkt. 3852, Alexander Rpt., Appx. F, ¶ 2 (citations omitted). Dr. Alexander’s expertise in this area is based on his training as a pharmacoepidemiologist, his “extensive experience in the role of pharmacies and pharmacists in the pharmaceutical supply chain,” and his experience conducting relevant research, including research related to automated algorithms to identify non-medical opioid use, and other topics listed above. Dkt. 3859, Alexander Tr. 150:12-13.

Plaintiffs would *not* offer remedy-related testimony by Dr. Alexander in Phase One of the trial (subparts *ii* and *iii* above). Nevertheless, Defendants ask the Court to preclude Dr. Alexander from testifying in Phase One on the basis that his opinions are “irrelevant” because they are “*primarily* about abatement.” Mot. 1 (emphasis added). However, that some of Dr. Alexander’s opinions are relevant to Phase Two, while others are relevant to Phase One, is no justification for completely barring him from testifying in Phase One.⁵ As mentioned, Plaintiffs would not elicit remedy-related testimony from Dr. Alexander in Phase One. At trial, the Court could police the line between the trial phases if necessary; for example, if any Defendant seeks to present evidence on apportionment. *See* Doc. 3579 at 5. At this juncture, there is no need for an order to “exclude” testimony that is not being offered and which under the Court’s existing orders already cannot be presented.

Defendants also argue that if Carmen Catizone’s opinions are excluded, Dr. Alexander’s opinions on potential indicators of high risk opioid distribution should also

⁵ The title of Defendants’ motion and the language of their Proposed Order imply that Defendants believe that “abatement opinions” and “Appendix F” cover the totality of Dr. Alexander’s opinions. However, as explained herein, Dr. Alexander offers other non-abatement opinions.

be excluded because “standing alone, [they have] no direct relevance to the issues in Track 3, as he has not in any way attempted to apply them to Defendants” Mot. 1. First, while Dr. Alexander references Dr. Catizone’s report, his conclusions are not premised on Dr. Catizone’s opinions. Dkt. 3859, Alexander Tr. 147:13-14 (“Appendix F represents my own beliefs, and I stand behind it.”); *id.* at 150:1-4 (“In other words, I didn’t need Mr. Catizone to tell me that when a patient fills both the benzodiazepine and a prescription opioid, they’re at much higher risk of potential trouble.”). Second, the connection of the indicators discussed by Dr. Alexander to Defendants is clear: They are “the types of indicators . . . that can be used by pharmacies and other actors in the pharmaceutical supply chain,” such as Defendants, to potentially identify high risk opioid distribution. *Id.* at 148:24-149:1. The indicators are highly relevant to the actions that Defendants did or did not take to fulfill their obligations to prevent diversion of opioids, which will be a subject of Defendants’ own employees’ testimony at trial. Therefore, whether or not Dr. Catizone’s testimony is admitted, Dr. Alexander’s testimony is relevant and would be helpful to the Court in understanding indicators of high risk opioid distribution and determining Defendants’ liability for the public nuisance.⁶

For the foregoing reasons, the Court should deny Defendants’ motion to exclude Dr. Alexander’s expert opinions.

Dated: August 18, 2021.

⁶ The only case Defendants cite in support of their argument, *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244 (6th Cir. 2001), concerned the testimony of an expert who purported to use a novel methodology to establish a causal relationship between PCBs and encephalopathy. Because he failed to account for potentially confounding factors and admitting that “no scientific literature supports his opinion,” the Sixth Circuit agreed with the magistrate judge that the expert’s opinions on causation were not reliable. *Id.* at 250-54. It is not apparent how that case supports Defendants’ position and they offer no explanation. Certainly, *Nelson* does not support the proposition that Dr. Alexander (who is not a causation expert) must prove Plaintiffs’ causation case in order to be allowed to testify. See *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010), as amended (Apr. 27, 2010) (“Reliable expert testimony need only be relevant, and need not establish every element that the plaintiff must prove, in order to be admissible.”).

Respectfully submitted,

Jayne Conroy
SIMMONS HANLY CONROY
112 Madison Avenue, 7th Floor
New York, NY 10016
(212) 784-6400
(212) 213-5949 (fax)
jconroy@simmonsfirm.com

Joseph F. Rice
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9000
(843) 216-9290 (fax)
jrice@motleyrice.com

Paul T. Farrell, Jr., Esq.
FARRELL & FULLER LLC
1311 Ponce de Léon Ave., Suite 202
San Juan, PR 00907
(304) 654-8281
paul@farrellfuller.com

Plaintiffs' Co-Lead Counsel

/s/Peter H. Weinberger
Peter H. Weinberger (0022076)
SPANGENBERG SHIBLEY & LIBER
1001 Lakeside Avenue East, Suite 1700
Cleveland, OH 44114
(216) 696-3232
(216) 696-3924 (fax)
pweinberger@spanglaw.com

Plaintiffs' Liaison Counsel

W. Mark Lanier
THE LANIER LAW FIRM

10940 Sam Houston Pkwy N., Suite 100
Houston, TX 77064
(713) 659-5200
(713) 659-2204 (fax)
Mark.Lanier@LanierLawFirm.com

Plaintiffs' Trial Counsel

Frank L. Gallucci
PLEVIN & GALLUCCI CO., L.P.A.
55 Public Square, Suite 222
Cleveland, OH 44113
(216) 861-0804
(216) 861-5322 (fax)
FGallucci@pglawyer.com

Hunter J. Shkolnik
NAPOLI SHKOLNIK
270 Munoz Rivera Avenue, Suite 201
Hato Rey, Puerto Rico 00918
(787) 493-5088, Ext. 2007
hunter@napolilaw.com

Salvatore C. Badala
NAPOLI SHKOLNIK PLLC
360 Lexington Ave., 11th Floor
New York, NY 10017
(212) 397-1000
(646) 843-7603 Fax
Sbadala@napolilaw.com

Counsel for Plaintiffs Lake County and Trumbull County, Ohio

On the Brief:

MOTLEY RICE LLC
Andrew P. Arnold
28 Bridgeside Blvd.
Mount Pleasant, South Carolina 29464
(843) 216-9000
aarnold@motleyrice.com